

CLAIMS

We claim:

1. A novel amorphous form of 1-amino-3, 5-dimethyltricyclo-[3,3,1,1^{3,7}]decane hydrochloride (memantine hydrochloride).
2. The amorphous form according to claim 1, characterized by an X-ray powder diffraction pattern substantially as depicted in Figure 1.
3. The amorphous form according to claim 1 containing less than about 10% crystalline forms of memantine hydrochloride.
4. The amorphous form according to claim 1 essentially free of crystalline forms of memantine hydrochloride.
5. The amorphous form according to claim 1 is anhydrous amorphous form or amorphous hydrate form of memantine hydrochloride.
6. A process for preparing an amorphous form of 1-amino-3, 5-dimethyltricyclo-[3,3,1,1^{3,7}]decane hydrochloride (memantine hydrochloride) comprising the steps of dissolving memantine hydrochloride in a solvent to form a solution, and removing the solvent from the solution to afford amorphous form of memantine hydrochloride.
7. The process of claim 6 wherein the solvent is removed by lyophilization.
8. The process of claim 7 wherein the solvent is an aqueous solvent.
9. The process of claim 8 wherein the aqueous solvent is water.
10. The process of claim 7 wherein the solvent is a C₁-C₄ alcohol.
11. The process of claim 6 wherein the solvent is removed by distillation.
12. The process of claim 11 wherein the solvent is an aqueous solvent.
13. The process of claim 11 wherein the solvent is a C₁-C₄ alcohol.
14. The process of claim 13 wherein the C₁-C₄ alcohol is methanol or ethanol.
15. The process of claim 11 wherein the distillation is performed at a pressure of about 400 mm Hg or less.
16. The process of claim 15 wherein the distillation is performed at a pressure of about 80 mm Hg or less.
17. The process of claim 11 wherein the distillation is performed at a pressure of from about 30 to about 80 mm Hg.
18. A pharmaceutical composition comprising an amorphous form of 1-amino-3, 5-dimethyltricyclo[3,3,1,1^{3,7}]decane hydrochloride (memantine hydrochloride) and pharmaceutically acceptable carrier, diluent, excipient, additive, filler, lubricant, solvent, binder or stabilizer.
19. A pharmaceutical composition according to claim 18, in the form of a tablet, troche, powder, syrup, patch, liposome, injection, dispersion, suspension, solutions, capsule, cream, ointment or aerosol.
20. A method for the treating or preventing cerebral ischemia after apoplexy, open-heart surgery, cardiac standstill, subarachnoidal hemorrhage, transient cerebro-ischemic attacks, perinatal asphyxia, anoxia, hypoglycemia, apnoea, non-ischemic neurodegenerative disease and moderate to severe Alzheimer's disease or conditions in which NMDA receptor antagonist is implicated, comprising administering an effective amount of an amorphous form of memantine hydrochloride according to any one of claims 1 to 5 and a pharmaceutically acceptable carrier, diluent, excipient, binder, additive, filler, lubricant, solvent or stabilizer to a patient in need thereof.